APPENDIX F

Issues to Consider When Outsourcing Reference Samples

There are many issues a laboratory director must consider when making the decision to send mass fatality samples to an outside vendor for short tandem repeat (STR) analysis testing. This list of issues is not meant to be inclusive; rather, it is offered as a starting point to aid in considering the use of a vendor laboratory to test personal items, reference samples, or remains samples.

Tasks and Requirements

- What standards of quality assurance are to be met.
- What certification will be provided that testing is performed in accordance with quality assurance standards.
- Specific tasks (for example: "The Vendor shall analyze all samples for the 13 CODIS core STR loci plus Amelogenin—FGA, vWA, D3S1358, CSF1PO, TPOX, THO1, D18S51, D21S11, D8S1179, D7S820, D13S317, D5S818, and D16S539—in accordance with the Federal Bureau of Investigation's NDIS [National Data Index System] Standards for Acceptance of DNA Data and the Contracting Agency/Vendor Testing and Reporting Guide.")
- Accreditations/certifications that the vendor laboratory should maintain, and penalties if accreditation/certification is not maintained.
- Timeframe for analysis and reporting turnaround (for example, "x" kinship samples per week, etc.).
- External proficiency testing program(s) that the vendor must complete during a specific timeframe, along with terms for submitting a certified statement of compliance and documentation of any failed proficiency tests and the remediation that was done to resolve the issue(s).
- Terms regarding the individual DNA analyst's compliance with a semiannual external proficiency testing program.
- Requirements that changes in the vendor's key personnel (specific personnel) be approved.
- Protocols and procedures for making analysis of the samples, quality control documents, and validation documentation available for review, inspection, and monitoring, including onsite reviews of the vendor's facility and records.
- Standard operating procedures and quality assurance procedures (including any changes made during the process) with respect to the receipt and analysis of samples.
- Terms regarding the vendor's ability to subcontract (or prohibition against subcontracting) any portion of the testing or analysis of the samples to any other laboratory without prior written authorization.
- Format for processing samples (for example, "Whole blood in tubes that the vendor shall be required to stain onto cotton fabric, 903 S&S paper, FTA paper," etc.; buccal swabs on a swab or placed on 903 S&S paper or FTA paper; extracted DNA; personal items (toothbrushes, hair brushes, clothing); victim bone and tissue, etc.)
- Preprinted shipping labels and shipping containers, and requirements regarding notification of when a shipping container is received, including notification upon discovery of any damage to the shipping container that would compromise the integrity of a sample.
- Chain-of-custody documentation, including, for example, a unique identifier on the overnight shipping label, sample receipt (and verification of seal integrity), sample transfers during processing, analysis and reporting, and return of the samples and resulting data.
- Storage of samples.
- Use of automated transfers (for example, use of a "plate fingerprinting" system to uniquely identify a 96-well plate, including the strategic placement of known controls on a 96-well

plate in a manner that allows any plate mixup to be detected).

- Use of NDIS-approved STR analysis kits specified in the NDIS Standards for Acceptance of DNA Data; if applicable, use of NDIS-approved STR analysis platforms and expert systems.
- Analytical procedures (for example, using appropriate controls and standards on each gel/run/batch; each sample used in reporting having an acceptable extraction positive, extraction negative, amplification positive, amplification negative, and ladder associated with each locus, and, if a sample is rerun, all controls to be rerun).
- The manner in which data are to be reported (for example, genotypes to be compiled in the common message format for insertion into the FBI's Combined DNA Index System (CODIS) and transmitted in electronic form (floppy disk, CD–ROM, a ZIP disk, secure Web site, or other method); cost of CD–ROM or ZIP disks and shipping to be included in the proposed cost per sample of completed analysis).
- Return of extraction, amplification, gel data sheets (including spreadsheets, original gel scans, and the final gray-scale/color-corrected gel images), and electropherogram data; return of instrument data collection files and files generated in the analysis of the samples in a prescribed form (CD–ROM, ZIP disk, posted to a secure Web site, etc.); return of samples, DNA extracts, amplified product, etc.
- Determination of when the analysis of a specimen is considered complete (for example, not until genotypes for all 13 CODIS core STR loci (plus Amelogenin) have been generated and accepted; requirements for when a sample does not yield a complete profile (for example, retest the sample a minimum of two times, altering conditions within the boundaries of the laboratory's written standard operating procedures, as necessary, to produce a complete profile, etc.).
- Terms for analysis failure (requests for additional samples, etc.).
- Sample shipping responsibilities (method, chain-of-custody safeguards, timeliness, tracking, etc.).
- Confidentiality of samples and the results of testing, including handling outside inquiries.
- Ownership of data, materials, and documentation.
- Procedures for notification regarding problems in testing.
- Contamination quality assurance checks.
- Retention of testing and quality control records.
- Written weekly reports, including changes to management and key personnel; assessment of technical risks and analytical and quality control processes; description of analytical errors detected during processing and corrective action taken; customer service logs; and performance metrics by sample type (reference, disaster, personal items), including, for example:
  - Number of samples received.
  - Running total for samples received.
  - Number of samples reported.
  - Number of failed samples (for example, those in which no profile or an incomplete profile—not all 13 CODIS core loci + Amelogenin—was generated.
  - Number of samples received more than 30 days ago, but not yet tested, analyzed, and reported.
  - Biweekly briefings.

Deliverables and Delivery Schedule

- Testing, analysis, and reporting services, including shipping; DNA profile; quality control results and records; testing and chain-of-custody documentation; data generated during the receipt, testing, analysis, and reporting; and unused samples.

Suspension and Termination

- Terms for suspension or termination for poor performance, including quality issues, customer service complaints, and inability to meet sample throughput commitments.

Equipment and Materials

- Who will furnish equipment and materials.

Security, Place of Performance, and Period of Performance

Here is a sample vendor testing and reporting guide that may contain components that laboratory directors may consider when contracting with an outside vendor.

(One form for each sample type: family reference, disaster, personal item)

Sample Type_____

1. Samples will be provided to the vendor in the following manner:

2. Samples will come from the following agencies/locations:

3. Samples will be provided to the vendor at the rate of:

4. Samples will be provided with the following identification, which shall be reported with the profile:

5. Samples will be rejected by the vendor for testing for the following reasons, with the following course of action:

6. No more than ___ percent of a sample shall be consumed by the vendor without permission.

7. DNA shall be extracted to a final volume of _____ at a concentration of _____.

8. The following DNA aliquots shall be made for additional testing:

9. The vendor shall use only the following testing and analysis systems:

   Extraction method:

   Amplification conditions (including kit and amplification volume):

   Analysis platform:

   Conditions for retesting if a complete profile is not initially obtained:

10. Procedural changes affecting sample processing must be approved ___ days prior to the processing of samples.

11. Manual transfer shall be allowed only during the following steps:

12. Spiking or enriching a sample is acceptable ___yes ___no.

    Comments:

13. Vendor controls:

    a. Amplification positive

       Name:
       When introduced:
       Considered acceptable when:
       Location on analysis:
       Location in data files:
       Acceptable results:

    b. Amplification negative

       Name:
       When introduced:
       Considered acceptable when:
       Location on analysis:
       Location in data files:
       Acceptable results:

    c. Extraction positive

       Name:
       When introduced:
       Considered acceptable when:
       Location on analysis:
       Location in data files:
       Acceptable results:

    d. Extraction negative

       Name:
       When introduced:
       Considered acceptable when:
       Location on analysis:
       Location in data files:
       Acceptable results:

    Other:

       Name:
       When introduced:
       Considered acceptable when:
       Location on analysis:
       Location in data files:
       Acceptable results:

A data file is defined as _____.

14. Samples with the following microvariants do not need to be retested:

15. Samples with trialleles shall be processed in the following manner:

16. Samples with triallelic profiles ___shall ___do not need to be retested. The following documentation shall be reported:

17. Samples with microvariants (not on an approved list) ___shall ___do not need to be retested. The following documentation shall be reported:

18. Profiles exhibiting multiple contributors shall be handled in the following manner:

19. Data analysis:

    a. General peak characteristics

       The following reporting criteria apply to:

       _____ Samples

       _____ Ladders

       _____ Controls

       _____ Internal size standard

       Minimum peak height:
       Maximum peak height:
       Shape:

       Spikes ___not allowed ___allowed under the following circumstances:

    b. Internal size standard

       The following peaks are required to be present for reported samples:

       Size of 245 peak (on 310) must be _____.

    c. Allelic Peaks

       Stutter:

       –A:

       Minimum allowable peak height ratio:

20. Data reporting

    a. Composite profiles (instances where the 13 CODIS core loci are created from more than the minimum multiplex data file[s] because one or more of the loci do not meet reporting criteria) ___shall ___ shall not be acceptable unless:

    b. Nonreported samples ___ may ___shall not be intermixed in reported data files.

    c. Data from all sample runs ___must ___need not be provided.

    d. Minimum and maximum number of reportable samples with complete profiles in a single data file is:

    e. Minimum and maximum number of samples (complete 13 locus profile) in a reported batch:

    f. The following documentation shall be provided/associated with the reported profiles:

    g. Data and data files shall be reported in the following format:

    h. Data shall be reported at a frequency of:

21. Samples shall be returned on the following date and in the following condition:

22. Other: